DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 21, 2015

LEVO AG
Andrew Dvorak
Engineer
Anglikerstrasse 20
CH-5610 Wohlen, Switzerland

Re: K140706
Trade/Device Name: LEVO MAX (MAX 100, MAX 200, MAX 300)
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: December 10, 2014
Received: December 17, 2014

Dear Mr. Dvorak:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Felipe Aguel -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140706

Device Name
LEVO MAX (MAX 100, MAX 200, MAX 300)

Indications for Use *(Describe)*
The LEVO MAX power wheelchair is intended to provide indoor and outdoor mobility to persons limited to a sitting position, that are capable of operating a powered wheelchair.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Submitter: LEVO AG
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Contact Person: Mr. Andrew Dvorak, Engineer
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Date Prepared June 27th, 2014

Device Name: **LEVO** *MAX*

Common name: Power Wheelchair

Classification Name: Wheelchair, Powered; (21 CFR 890.3860, Product Code ITI)

Predicate Devices:
Permobil M400(K123290)

Intended Use: The **LEVO** *MAX* power wheelchair is intended to provide indoor and outdoor mobility to persons limited to a sitting position, that are capable of operating a powered wheelchair.

Technological Characteristics and Substantial Equivalence

Device Description: The **LEVO** *MAX* powered wheelchair with optional seating and function is center wheel motor driven, battery powered, motor driven power wheelchair and is controlled by the PG Drives Technology's power wheelchair controller "R-net" or "VR2". The joystick user interface is integrated in the controller. The wheelchair is powered by two 12V/55Ah, 12V/73Ah or two 12V/75Ah batteries with a theoretical driving range of 25km (55Ah), 35km (72Ah); with fully charged batteries.

Components: The **LEVO** MAX power wheelchair consists of three basic sub-sections. These are: the base with drive units, the PG Drives Technology's R-NET or VR-2 Control System, and the body supporting system.

The base of the **LEVO** MAX includes: the frame, two direct-drive units with integrated parking brakes, two 12V/55Ah, two 12V/73Ah, or two 12V/75Ah batteries, two straight front and two center driving wheels as well as two twin rear caster wheels.

PG Drives Technology's VR2-Control System includes the power module, the integrated lighting module and the controller with integrated joystick. PG Drives Technology's R-NET

Control System includes the power module, the intelligent seating/lighting module and the controller with integrated joystick.

The body supporting system includes the seat support, the back support, armrests and leg rests.

Performance Data:
Testing was performed in accordance with the following standards:

- RESNA WC-1:2009 Section 1: Determination of static stability.
- RESNA WC-2:2009 Section 2: Determination of dynamic stability of electrically powered wheelchairs.
- RESNA WC-2:2009 Section 3: Determination of effectiveness of brakes.
- RESNA WC-2:2009 Section 4: Energy consumption of electrically powered wheelchairs and scooters for determination of theoretical dis.
- RESNA WC-1:2009 Section 5: Determination of dimensions, mass and maneuvering space
- RESNA WC-2:2009 Section 6: Determination of maximum speed, acceleration and deceleration of electrically powered wheelchairs
- RESNA WC-1:2009 Section 7: Method of Measurement of Seating and Wheel Dimensions
- RESNA WC-1:2009 Section 8: Requirements and test methods for static, impact and fatigue strength
- RESNA WC-2:2009 Section 10: Determination of obstacle-climbing ability of electrically powered wheelchairs
- RESNA WC-1:2009 Section 11: Test dummies
- RESNA WC-1:2009 Section 13: Determination of coefficient of friction of test surfaces
- RESNA WC-2:2009 Section 14: Power and control systems for electrically powered wheelchairs Requirements and test methods.
- RESNA WC-1:2009 Wheelchairs - Part 15: Requirements for information disclosure, documentation and labeling
- RESNA WC-1:2009 Section 16: Resistance to ignition of upholstered parts - Requirements and test methods
- RESNA WC-1:2009 Section 22: Set-up procedures
- RESNA WC-1:2009 Section 26: Vocabulary

- ISO 7176-1:1999 Wheelchairs - Part 1: Determination of static stability
- ISO 7176-2:2001 Wheelchairs - Part 2: Determination of dynamic stability of electric wheelchairs
- ISO 7176-3:2012 Wheelchairs - Part 3: Determination of efficiency of brakes
- ISO 7176-4:2008 Wheelchairs - Part 4: Energy consumption of electric wheelchairs and scooters for determination of theoretical distance range
- ISO 7176-5:2008 Wheelchairs - Part 5: Determination of overall dimensions, mass and turning space
- ISO 7176-6:2001 Wheelchairs - Part 6: Determination of maximum speed, acceleration and deceleration of electric wheelchairs
- ISO 7176-7:1998 Wheelchairs - Part 7: Measurement of seating and wheel dimensions
- ISO 7176-8:1998 Wheelchairs - Part 8: Requirements and test methods for static, impact and fatigue strengths
- ISO 7176-10:2008 Wheelchairs - Part 10: Determination of obstacle climbing ability of electric wheelchairs
- ISO 7176-11:2012 Wheelchairs - Part 11: Test dummies

- ISO 7176-13:1989 Wheelchairs - Part 13: Determination of coefficient of friction of test surfaces
- ISO 7176-14:2008 Wheelchairs - Part 14: Power and control systems for electric wheelchairs - Requirements and test methods
- ISO 7176-15:1996 Wheelchairs - Part 15: Requirements for information disclosure, documentation and labeling
- ISO 7176-16:2012 Wheelchairs - Part 16: Resistance to ignition of upholstered parts – 1-2
- ISO 7176-19:2008 Wheelchairs – Part 19 Wheeled Mobility Devices for use as seats in motor vehicles
- ISO 7176-22:2000 Wheelchairs - Part22: Set-up procedures
- EN 12184:2009 Electrically powered wheelchairs, scooters an their chargers
- EN 12182:2012 Technical aids for disabled persons. General requirements and test methods

In all instances of the above mentioned test criteria, the Levo MAX functioned as intended.

Performance Data continued:
Testing will be conducted and meet the acceptance criteria of the following standards before the device is marketed:

- RESNA WC-2:2009 Section 9: Climatic tests for electrically powered wheelchairs
- RESNA WC-2:2009 Section 21: Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs
- ISO 7176-9:2009 Wheelchairs - Part 9: Climatic tests for electric wheelchairs
- ISO 7176-21:2009 Wheelchairs - Part21: Requirements and test methods for electromagnetic compatibility

Substantial Equivalence:

The **LEVO** MAX is substantially equivalent to the cleared predicate devices, the Permobil M400, as outlined in the following table:

Characteristic	**LEVO** MAX	Permobil M400
Intended use	The LEVO MAX power wheelchair is intended to provide indoor and outdoor mobility to persons restricted to a sitting position that are capable of operating a powered wheelchair.	To provide indoor and outdoor mobility to persons restricted to a sitting position that are capable of operating a powered wheelchair
Type of base	Mid wheel driven	Mid wheel driven
Caster wheel Dimension	7" twin	200x50 mm
Drive wheel Dimension	3.00-8"	3.00-8"
Adjustable Anti-Tip wheels	The front and rear wheels function as anti-tip devices	The front and rear wheels function as anti-tip devices
Over all Dimensions l/w/h (mm)	1300/620/1120	1256/620/1260
Weight incl. batteries	170 kg	155 kg

Weight bearing capacity	160 kg	136kg
Maximum Speed	Up to 12 km/h	Up to 12 km/h
Brake System	Electronic braking via drive motors and magnetic parking brakes	Electronic braking via drive motors and magnetic parking brakes
Ground clearance	72mm	77mm
Obstacle climbing	130mm	70mm
Turning Radius	600mm	800mm
Driving Range	Up to 35 km	Up to 25 km

The **LEVO** MAX is substantially equivalent to the Permobil M400(#K123290). The **LEVO** MAX has the same intended uses and similar indications, technological characteristics and principles of operation. The minor technological differences between the **LEVO** MAX and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the **LEVO** MAX is as safe and effective as its predicate devices. Thus, the **LEVO** MAX, Permobil M400 are substantially equivalent.